

REMARKS

Applicants have carefully considered the matters raised by the Examiner in the outstanding Office Action but remain of the position that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the attached abstract, specification amendments, claim amendments and the following remarks.

At the outset, Applicants note that a response to the outstanding Office Action was due by November 13, 2003. Applicants have enclosed a one-month extension of time in order to extend the period of reply until Saturday, December 13, 2003. Thus, this response sent via Express Mail on Monday, December 15, 2003 is timely filed.

The present invention is directed to a process of production of a peptide of interest from a biological fluid.

Claims 1-11, 13 and 14 are pending in this Application. Claims 1-10 have been allowed. Claim 11 had been rejected as being anticipated by Kizawa. Claim 11, as well as the specification, had been objected to for failing to use a sequence identifier. Claims 1-11 and 13-14 had been rejected under 35 USC 112, second paragraph. Claims 11, 13 and 14 had been rejected under 35 USC 112, first paragraph. Finally, the Examiner had noted that no Abstract had been provided.

(A)

Kizawa had been cited for teaching peptides of the sequence VYQHQQAMKPWIQPKTKVIPYVRY and VYQHQQAMKPWIQPKTKVIPYVRYL.

These two peptide sequences read on two of the eight peptide sequences disclosed in claim 11. The Examiner, however, noted in paragraph 10 of the Office Action that the peptides of Kizawa are not produced by the process recited in product-by-process claim 11.

The process of the present invention provides peptides that are adsorbed in a chromatographic medium before hydrolysis. In contrast to the process of the present invention, conventional processes teach an initial hydrolysis followed by purification. It has surprisingly been found that by reversing the hydrolyzation and purification step of the original substrate the hydrolyzation resulted in different hydrolysates as compared with conventional processes. The peptides produced according to the process of the present invention therefore differ from conventional peptides and are thus novel due to the fact that the peptides of claim 11 exhibit a preferred biological activity achieved as a result of performing hydrolysis after chromatographic adsorption. Thus, Applicants submit that the peptides recited in claim 11 are patentable over Kizawa.

Claim 11, as well as the specification, had been objected to for failing to use a sequence identifier. Applicant has amended claim 11 and Tables 1-5 on pages 15-18 of the Application in order to add the appropriate sequence identification numbers. Support for this amendment can be found on page 13 where sequences (1) to (8) are described.

(B)

Claims 1-11 and 13-14 had been rejected under 35 USC 112, second paragraph as being indefinite. Specifically, the Examiner had stated that the process of claim 1 is a process of purification and not a process of production. Applicants respectfully submit that the process of the present invention can indeed be characterized as a process of production because claim 1 recites both a hydrolysis step and a purification step. In addition, “at least one peptide of interest” is produced from a hydrolysate obtained from the initial fluid. Applicants therefore submit that it is correct to refer to the process of claim 1 as a process of production of a peptide.

Claim 10 had been rejected because the Application states that the peptides can be produced from culture cells and plant cells which are not considered to be “biological fluids”. The Examiner also stated that culture cells and -plant cells contain biological fluids, but are not biological fluids themselves.

At page 9, paragraph 1, it is explained that for the purposes of the present invention, any fluid comprising proteins falls within the term “biological fluids” as used in the Application. Applicants have therefore chosen to define the term “biological fluids” very broadly, and this definition encompasses culture cells and plant cells containing biological fluids as recited in claim 10.

Claim 11 had been rejected as indefinite because the Examiner had stated that it is unclear as to which sequences that claim refers to. Claim 11 had also been rejected as

indefinite because the Examiner had stated that it is unclear as to the precise definition of the amino acid derivatives.

Applicants have amended claim 11 to more clearly refer to the amino acid sequences in accordance with the Examiner's request. The description of sequences (1) to (8) are now recited immediately after the phrase "selected from the following sequences. In addition, this amendment to claim 11 now makes clear that the term "derivative" as used in claim 11 refers to a derivative of the 8 defined peptides wherein the carboxylic group is replaced by a primary amino group. By definition, each of the 8 defined peptides have a terminal amino group at one end and a terminal carboxylic group at the other end. Applicants submit that it is now clear that the peptide derivatives of claim 11 refer to peptides having two amino groups, i.e., a primary amide replaces the carboxylic group.

Claim 11 had also been rejected as indefinite due to use of the "*" indicating a disulfide linkage between the two "C's" in amino acid sequence (5). Applicants submit that the meaning of the use of the "*" to indicate a disulfide linkage is conventional and adequately clear to one of skill in the art. "C" in sequence (5) refers to cysteine which can either be in the form of -SH or can form a -S-S- bridge with another cysteine molecule. The "*" clearly belongs to the "C" and refers to a compound which could alternatively be written with an extra line drawn between the two "C's" indicating the extra disulfide link between these molecules. Thus, Applicants submit that the "*" in claim 11 is clear to one of skill in the art.

Claims 11, 13 and 14 had been rejected under 35 USC 112, first paragraph, as containing subject matter that is not adequately described in the specification. Applicants have accordingly cancelled claims 13 and 14 in order to remove this rejection.

The Examiner had also noted that no Abstract had been provided. Applicants have herein provided an Abstract identical to the Abstract in the parent Application.

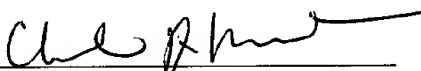
Finally, Applicants have amended claims 1, 5, 10 and 11 in order to correct a number of obvious typographical errors. In particular, sequences (5) and (8) of claim 11 had been incorrectly listed and corrected herein. Support for this amendment can be found on page 13 of the Application.

In view of the foregoing and the enclosed, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. Should any additional extensions of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit Account # 02-2275.

Respectfully submitted,

MUSERLIAN, LUCAS AND MERCANTI, LLP

By:


Charles A. Muserlian
Attorney for Applicant(s)
475 Park Avenue South
New York, New York
Tel. # 212-661-8000

Encl: Return receipt postcard